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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/659,379	09/08/2000	Aaron I. Vinik	05126.00003	4987

7590 12/04/2001

Banner & Witcoff Ltd
Eleventh Floor
1001 G Street NW
Washington, DC 20001-4597

EXAMINER
ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/659,379	Vinik et al.
Examiner	**Art Unit**
Hope Robinson	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 19, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-49* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. The consent of assignee to the reissue has been received.

2. This reissue application was filed without the required offer to surrender the original patent or, if the original is lost or inaccessible, an affidavit or declaration to that effect. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

3. Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 5,804,421, which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP 1404, 1442.01 and 1442.04.

4. The amendment filed July 19, 2001 proposes amendments to the claims that do not comply with 37 CFR 1.121(b) and 37 CFR 1.173, which sets forth the manner of making amendments in reissue applications. It is noted that applicant submitted new claims 48 and 49, however, they are not in proper amendment format for a re-issue application. Furthermore, it is

requested that applicant re-submit also the amendments to claims 7, 8 and 15 as they too are not in a proper format. A supplemental paper correctly amending the reissue application is required.

5. The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required. Note that the present Oath/Declaration has non-initialed changes. Thus, in accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

6. Claims 1-49 are rejected as being based upon a defective Oath/Declaration under 35 U.S.C. 251. See 37 CFR 1.175.

The nature of the defect(s) is in the failure of the Oath/Declaration to initial and date alterations made to the Oath/Declaration.

7. Claims 21, 22, 27 and 28 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball*

Corp. v. *United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application. Note that claims 21. 21. 27 and 28 with the recitation of " a portion" is improper recapture for broadening. This attempt to broaden the claims which was rejected in an office action in the parent file above in the re-issue application is a clear example of recapture, which is prohibited. In addition, claim 24 which also recites the language "portion of" also inappropriately broadens the claim. The claims of the issued patent are limited to and only enabled for SEQ ID NO: 6 and 4 (see for example Paper No. 9 of 08/741,096). Thus, this is an improper broadening of scope. In addition, these claims were specifically amended in the parent application 08/741,096 (ABN) on which 08/909,725 (Patent No. 5,804,421) claims priority as a continuation. Thus, this attempt to broaden back to the original scope is a clear case of recapture and is prohibited.

8. Claims 48 and 49 have been added. Claims 1-49 are pending.

9. The following grounds of rejection are or remain applicable :

Claim Objection

10. Claim 49 is objected to because the claim is not in sequence compliance. Although SEQ ID NO: 2 and 3 are set forth in the sequence listing, the recited sequence in the claim is not *per se* found as a separate sequence in the sequence listing. See 37 CFR 1.821(c) and (d). It is suggested that applicant delete the recited sequence (5'-GAA...ACT-3' etc.).

Oath/Declaration

11. The oath/declaration is objected to because there appears non-initialed and/or non-dated alterations to the oath/declaration. See 37 CFR 1.52(c).

Drawing

12. It is noted that applicant is requesting the transfer of formal drawings from the patent file, however, transfer of the drawings from the patent files will no longer be made by the PTO. Therefore, formal drawings need to be submitted.

Specification

13. The specification is objected to because of the following informalities:

The disclosure is objected to because "INGAP protein" is disclosed. Note that the recitation of "INGAP" is sufficient as it means "islet cell neogenesis protein". It is suggested that applicant delete the word protein following the acronym.

Correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-49 are rejected under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses that the present invention is directed to a method of producing biologically active INGAP and to provide a recombinant construct for expression of biologically

active INGAP, however, neither the specification nor the claims describes the INGAP activity (see for example claim 1). Further, the claims recite an islet cell neogenesis associated protein (INGAP) and the specific sequence with no limitation to the function of the protein (see claims 1, and 21). In addition, claims 21 and 23-26 recite a human INGAP coding sequence and no sequence or characteristics (i.e. size/length) of the "portion" is provided (see claim 29). Moreover, claims 21-28 are directed to oligonucleotide primers that hybridize and the claims do not recite a hybridization condition or whether this refers to high or low stringency. Furthermore, the specification does not provide any information as to the hybridization conditions and it is well known in the art the hybridization conditions vary.

As the disclosure does not adequately describe the claimed invention with respect to the hybridization conditions, the activity of the protein or any characteristics of the claimed portion, one of skill in the art would have to engage in undue experimentation to practice the claimed invention.

15. Claims 21, 23 and 24-47 remain rejected under 35 U.S.C. 112 first paragraph, because the specification, while being enabling for a method of making an expression construct with using SEQ ID NO: 6, does not reasonably provide enablement for all expression constructs that produce Islet Neogenesis Associated Protein (INGAP). The claims of the issued patent are limited to and only enabled for SEQ ID NO: 6 and 4. Thus, the specification does not enabled any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In addition, claim 21 contains no sequence reference and thus is also too broad. In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include: Quantity of Experimentation Necessary, Amount of direction or guidance presented, Presence or absence of working examples, Nature of the Invention, State of the prior art and Relative skill of those in the art, Predictability or unpredictability of the art and Breadth of the claims.

The specification only teaches two polynucleotides, SEQ ID NO: 4 and 6, but the claims are also drawn to SEQ ID NO: 4 variants which encompasses thousands of sequences. The specification does not provide any examples of methods that may be used to determine the critical percent identity that must be maintained in making these conservative substitutions and retain the desired function. The specification also does not give any guidance concerning structural or functional parameters/features the polypeptides must retain that would allow one skilled in the art to identify them as OFQ receptors.

Based on the specification, these are novel proteins, as evidenced by the statement "[Specifically disclosed therein are nucleic acids encoding the novel mammalian receptor gene (see page 2, last sentence). The novelty of proteins is further evidenced by an absence in the prior art of SEQ ID NO: 4, nor does the prior art teach a particular or common structure or functional

feature that can be used to identify these molecules. Therefore, with assistance from the prior art one skilled in the art must rely wholly on the teachings in the instant specification to enable all of the molecules encompassed in the claims.

As taught by Burgess (J. Cell Biology, vol. 111, page 2129, 1990) recombinant technology and amino acid sequences in particular are highly unpredictable, as witnessed by the fact that the replacement of a single lysine residue at position 132 of heparin-binding growth factor-1 leads to a substantial loss of target binding and biological activity (see pages 2132-2133). There is an inverse relationship in regard to level of unpredictability in the art and the amount of guidance and direction necessary to enable claims with such a broad scope as in the instant case.

Thus, the specification does not provide an enabling disclosure commensurate in scope with the claims and is therefore, rejected.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the claim recites "INGAP activity" without reciting what "activity" is being referred to. In addition the claim is indefinite for the recitation of "amino acids 27 to 175" instead of reciting "amino acid residues 27 to 175" (see also column 3, lines 8-9, "the coding sequence of amino acids residues 27-175 of INGAP are included in the constructs"), see also claims 13, 15-18, 29 and 48. The dependent claims are included in this rejection.

Claim 2 is indefinite because the claims depends from claim 1 and broadens claim 1. Note that claim 1 recites "is not present immediately 5' of said first nucleotide sequence" and claim 2 recites "are not present 5' of said first nucleotide sequence", and this terminology is broader. It is suggested that applicant amend the claim to recite the terminology of claim 1 (see also claim 30).

Claim 6 is indefinite for the recitation of "promoter/operator" as it is unclear if the slash mark refers to "and" or "or" (see also claims 26, 34 and 41).

Claims 7 and 8 lacks antecedent basis for "transcriptional initiation site" inserted into the claims based on the proposed amendments to the claims because column 3, lines 40-45 of the patent (5,804,421) discloses that "[F]or eukaryotic expression system, it is exceedingly useful to choose a promoter sequence which is capable of initiating constitutive transcription to achieve constitutive high level expression of the protein. Rous sarcoma virus long terminal repeat

(RSVLTR) is an example of such promoter, although others as are known in the art can be used". Therefore, there is no support for the insertion of "transcriptional initiation site". As applicant stated on the Declaration that" claims 7 and 8 improperly refer to an additional element (a promoter sequence) which is in actuality already recited in independent claim 1 (as a transcriptional initiation site); therefore the promoter sequence is not an additional element", it is suggested that applicant delete claims 7 and 8 as they are not further limiting, but to add the words "transcriptional initiation site" to the claims is not supported by the specification (see also claims 35 and 36).

Claim 10 is indefinite for the recitation of EBNA-1 without the corresponding spelled out meaning (see also claim 38).

Claim 13 is indefinite because the claim recites "islet cell neogenesis associated **protein** (INGAP) **protein**, or **INGAP protein**". Note that the recitation of "INGAP" is sufficient as it means "islet cell neogenesis protein". It is suggested that applicant delete the word protein following the acronym (see also claims 14, 45 and 46). The dependent claims are also included in this rejection.

Claims 6, 19, 26, 34 and 41-44 lack antecedent basis for "transcription initiation site", as the disclosure of the patent in column 2, lines 42-45 state that "[S]uitable inducible transcription initiators include the lac promoter/operator, the tac promoter, the trp promoter, the λcI promoter, the tet promoter, as well as others which are known in the art".

Claim 21 is indefinite because the claim recites "oligonucleotide primers hybridizes" without providing the hybridization conditions. Furthermore, the claim remains indefinite because there is no recitation of a sequence in the claim (see also claims 23-47). The claim is also indefinite for the recitation of "a portion of the human INGAP" and there is no indicia of the size/length of the portion (see also claim 27).

Claim 49 is indefinite for the recitation of "SEQ ID NO.:2", note that the sequence number is inappropriately spaced with the notation "SEQ ID NO" and only a colon should appear not a colon and period before the number. The claim is further indefinite as to the extraneous period following "SEQ ID NO.", because it is unclear if applicant intends for the sentence to end here.

Claim 23 is indefinite for the recitation of "forming/form" in the method rather than "making/make" with regard to the expression construct as applicant intend to create the expression construct. The dependent claims are included in this rejection.

The Basis For Non-Statutory Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 09/717,095. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are directed to a recombinant construct for expression of INGAP which comprises a nucleotide sequence that encodes the amino acids set forth in SEQ ID NO: 6. Note that the copending application is directed to an isolated DNA molecule which encodes an INGAP protein set forth in SEQ ID NO: 2 and both sequences are identical with the exception of one residue (SEQ ID NO: 6 has an additional Methionine in the beginning of the sequence). Note also that the claims in both applications are directed to fragments (portions) of the claimed sequences. Furthermore, the present application and copending application both claim probes, primers and have claims directed to antisense strands which would render each other obvious. Although the claims in the two applications are not identical the claimed subject matter in both applications are an obvious variation of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,840,531. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are directed to a recombinant construct for expression of INGAP which comprises a nucleotide sequence that encodes the amino acids set forth in SEQ ID NO: 6. Note that the patented claims are directed to an isolated DNA molecule which encodes an INGAP protein set forth in SEQ ID NO: 2 and both sequences are identical with the exception of one residue (SEQ ID NO: 6 has an additional Methionine in the beginning of the sequence). Furthermore, the present application and patent both have claims which are directed to probes, primers and antisense strands which would render each other obvious. Although the claims in the present application and the patent are not identical the claimed subject matter in both are an obvious variation of each other.

Additionally, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. In re Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP 804.

20. Applicant's arguments filed July 19, 2001 in Paper No. 4 have been considered. Note that applicant's amendment and arguments were not sufficient to overcome the rejections of record. Note also that new grounds of rejections have been instituted. With regard to the rejection remaining under 35 U.S.C. 112, first paragraph, applicant's argue that those skilled in the art wold know how to allelic variants and that INGAP was part of the stat of the art, thus those of ordinary skill would be able to use INGAP and its obvious variants. Applicant also contends that a molecular biologists generally have Ph.D.s plus several years of post-doctoral training and INGAP was known. As stated in the prior office action the art is very unpredictable and as no analogous art was found teaching SEQ ID NO: 4. Furthermore, the response is confusing as applicant refers to those of ordinary skill in the art and then refers to a person who holds a Ph.D. and post-doctoral training. Applicant also contends that the claims are narrow, however, claim 21 is very broad. With regard to the issue of recapture, the response argues that the claims were not disclosed in the parent applications, thus does not present this problem. Applicant's arguments are not convincing as the office in application 08/741,096 (for which 08/909,725 claims priority) told applicant that the specification was enabled for the specific construct based on a particular sequence (with a particular numbering system)and was not enabled for expression of any INGAP activity from any source using any host organism. Note that claims 21-22 are directed to a "portion" of the human INGAP coding sequence. Thus, the application has recaptured an abandoned invention. Thus, the rejection has been maintained.

Regarding, the rejection under 35 U.S.C. 112, second paragraph, applicant's response argues that the structure of INGAP was known in the art as of the effective filing date of the application. However, this argument is not convincing because the claims are directed to a "portion" of the human INGAP coding sequence without identifying the sequence which renders the claims indefinite.

Conclusion

21. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday and Wednesday- Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS

Patent Examiner

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600